4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Center for Biologics Evaluation and Research (CBER), Office of Tissues and Advanced Therapies (OTAT) has modified its organizational structures.

DATES: These new organizational structures were approved by the Secretary of Health and Human Services on August 8, 2022, and effective on September 16, 2022.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management, Office of Finance, Budget, Acquisitions and Planning, FDA, 4041 Powder Mill Road, Beltsville, MD, 20705-4304, 301-796-3843.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect the Food and Drug Administration's reorganization of CBER, Office of Tissues and Advanced Therapies (OTAT).

CBER's mission is to protect and enhance public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. With substantial growth in innovative, novel products, as well as a need to

address an ever-changing landscape of potential public health threats, CBER is currently facing scientific, medical, and regulatory challenges that require changes to its structure.

Utilizing key tenets of CBER's modernization efforts, CBER will retitle OTAT to the Office of Therapeutic Products (OTP) and elevate OTP to a Super Office to manage its program at a macro level and to better position the Center to address an everchanging public health landscape. With the current and anticipated increase in workloads, the proposed structural changes will improve functional alignment, increase review capabilities, and enhance expertise on new cell and gene therapies. Additional supervisory positions will not only help to address this increased workload but will also provide advancement opportunities to facilitate recruitment and retention of highly qualified staff. The proposal creates flexibility and capacity for future growth in Full-Time Employees (FTEs) and workload, avoiding the need for continual reorganizations. The reorganization will position OTP to focus on commitments, including those negotiated with industry in the prescription drug user fee agreement (PDUFA) for FY 2023-2027, and other key priorities that protect public health. To advance the field and support the next generation of cell and gene therapies, OTP will continue to see growth in the Regenerative Medicine Advanced Therapy (RMAT) program, established in the 21st Century Cures Act.

The Food and Drug Administration's Center for Biologics Evaluation and Research, Office of Tissues and Advanced Therapies, has been restructured as follows:

DCB. ORGANIZATION. The Center for Biologics Evaluation and Research is headed by the Center Director, Center for Biologics Evaluation and Research.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (DCB)

Office of Therapeutic Products (DCBG)

Administrative Staff (DCBG1)

Policy and Special Projects Staff (DCBG2)

Office of Gene Therapy CMC (DCBGF)

Division of Gene Therapy I (DCBGFA)

Gene Therapy Branch 1 (DCBGFA1)

Gene Therapy Branch 2 (DCBGFA2)

Gene Therapy Branch 3 (DCBGFA3)

Division of Gene Therapy II (DCBGFB)

Gene Transfer and Immunogenicity Branch (DCBGFB1)

Gene Therapy Branch 4 (DCBGFB2)

Gene Therapy Branch 5 (DCBGFB3)

Office of Cellular Therapy and Human Tissues CMC (DCBGG)

Division of Cell Therapy I (DCBGGA)

Cell Therapy Branch 1 (DCBGGA1)

Cell Therapy Branch 2 (DCBGGA2)

Cellular and Tissue Therapy Branch (DCBGGA3)

Division of Cell Therapy II (DCBGGB)

Tissue Engineering Branch 1 (DCBGGB1)

Tissue Engineering Branch 2 (DCBGGB2)

Tumor Vaccine and Biotechnology Branch (DCBGGB3)

Division of Human Tissues (DCBGGC)

Human Tissues and Reproduction Staff (DCBGGC1)

Office of Plasma Protein Therapeutics CMC (DCBGH)

Division of Hemostasis (DCBGHA)

Hemostasis Branch 1 (DCBGHA1)

Hemostasis Branch 2 (DCBGHA2)

Division of Plasma Derivatives (DCBGHB)

Plasma Derivatives Branch 1 (DCBGHB1)

Plasma Derivatives Branch 2 (DCBGHB2)

Office of Clinical Evaluation (DCBGI)

Division of Clinical Evaluation General Medicine (DCBGIA)

General Medicine Branch 1 (DCBGIA1)

General Medicine Branch 2 (DCBGIA2)

General Medicine Branch 3 (DCBGIA3)

General Medicine Branch 4 (DCBGIA4)

Division of Clinical Evaluation Oncology (DCBGIB)

Oncology Branch 1 (DCBGIB1)

Oncology Branch 2 (DCBGIB2)

Division of Clinical Evaluation Hematology (DCBGIC)

Benign Hematology Branch (DCBGIC1)

Malignant Hematology Branch (DCBGIC2)

Office of Pharmacology/Toxicology (DCBGJ)

Division of Pharmacology/Toxicology I (DCBGJA)

Pharmacology/Toxicology Branch 1 (DCBGJA1)

Pharmacology/Toxicology Branch 3 (DCBGJA2)

Division of Pharmacology/Toxicology II (DCBGJB)

Pharmacology/Toxicology Branch 2 (DCBGJB1)

Pharmacology/Toxicology Branch 4 (DCBGJB2)

Office of Review Management and Regulatory Review (DCBGK)

Division of Review Management and Regulatory Review I (DCBGKA)

Regulatory Review Branch 1 (DCBGKA1)

Review Management Support Branch 1 (DCBGKA2)

Division of Review Management and Regulatory Review II (DCBGKB)

Regulatory Review Branch 2 (DCBGKB1)

Review Management Support Branch 2 (DCBGKB2)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.(Authority: 44 U.S.C. 3101)

Dated: September 23, 2022.

Xavier Becerra,

Secretary of Health and Human Services.

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